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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/583,263	05/31/2000	Chicheng Wang	1225.003US1	2811

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FULWIDER PATTON LEE & UTECHT, LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE
TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant N .

09/583,263

Applicant(s)

WANG, CHICHENG

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-21 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6, and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Dayton (5,578,075). With respect to claims 1-3, 6, 12, and 13, Dayton discloses, in figures 8-10 and in col. 7, lines 34-55, a stent with a structural support (11) with an outer surface comprising patterns of raised triangles (20) and slots and a polymeric film overlaying the support. With respect to claims 8 and 9, col. 6, line 66 to col. 7, line 34 disclose polymeric films and drugs as claimed. With respect to claim 10, col. 8, lines 16-21 disclose that the polymeric film covers apertures or holes in the support, and the film itself can have holes; so the film defines apertures. With respect to claim 11, col. 7, lines 60-63 disclose that the stent is expandable. Therefore, a polymeric film, which can be described as a sleeve on the stent, is expandable.

3. Claims 1, 8, 15, 16, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaster (4,441,215). Figures 2-4, col. 6, lines 33-44, and col. 7, line 11-35, disclose a stent or stent assembly and a method of adhering a polymeric tube (30 or 32) to a stent structural member (10) with a raised textured or herringboned design of braided filaments, where the tube comprises latex, urethane, or polytetrafluorethylene.

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4. Claims 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan (5,843,172). Figures 1 and 4-8; col. 1, lines 55-57; col. 4, line 66 to col. 5, line 29; and col. 9, lines 16-50 disclose an expandable stent assembly with a structural member (12) with a roughened or texturized surface, an expandable polymeric sleeve or sheet (see col. 9, lines 41-50 for films that are formed into sleeves or sheets encapsulating an expandable structural member), and drugs contained by the sleeves or sheets.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dayton in view of Williams (5,423,885). Dayton discloses the invention substantially as claimed, but does not disclose an outer surface and the ends of a structural support that are covered by raised triangles. Williams teaches, in the figures, a structural support

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with an outer surface and ends covered by raised triangles. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Williams, to modify the structural support of Dayton, so that the outer surface and the ends are covered by raised triangles. Such a modification would produce a structural support that would be strongly secured to a desired location in a blood vessel upon deployment of the support.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dayton. Dayton discloses the invention substantially as claimed, but does not specifically disclose raised triangles that are raised from about .001 inch to about .005 inch. Nevertheless, it would have been a matter of design choice on the part of a surgeon to configure the raised triangles as claimed. The choice would be dependent upon the type and size of tissue being supported by a stent.

Allowable Subject Matter

8. Claim 22 is allowed.

9. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination discloses, inter alia, a structural support of a stent having an outer surface with a pattern of raised squares.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

11. Applicant's arguments with respect to claims 1, 8, 15, 16, and 19 have been considered but are moot in view of the new ground(s) of rejection.

Additionally, with respect to arguments regarding claims rejected on references, Dayton and Dayton in view of Williams: The surface of Dayton's stent is also patterned with holes or slots, which are filled or covered with a polymeric film (i.e. the film is retained by the holes), which in turn, produces a smooth surface. Also, the tabs taught by Dayton, not only prevent the stent from recoiling, they provide surfaces and gaps for retaining the film or coating.

With respect to arguments regarding claims rejected on the Yan reference: The porous cavities of Yan's stent do not retain therapeutic agents exclusively. Col. 9, lines 41-50 disclose that the porous cavities can retain films intermixed with the agents or films and agents separately.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bokros et al. (4,164,045) teach a stent with a roughened surface and a polymeric coating.

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13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9302.

A handwritten signature in black ink, reading "Julian W. Woo". The signature is written in a cursive, flowing style with a long horizontal stroke at the end.

Julian W. Woo
Patent Examiner

November 5, 2002